

**REMARKS**

Claim 14 is amended and new claims 18 – 23 are presented; claims 1-7, 9, and 13-23 are before the examiner.

Claim 14 is amended into a form similar to that presented in the un-entered after-final amendment of November 7, 2007; claim 11 from the same un-entered amendment, which was subsequently canceled, is re-presented as new claim 18. Thus, the present claims 1-7, 9, and 13-18 correspond to those presented in the un-entered amendment of November 7, 2007, which was refused entry by the examiner as raising new issues.

In addition, new claims 19 and 23 are similar in scope to the implantation and extraction methods of claims 16 and 17, respectively, but depend from claim 5 and independently recite the applicable manipulation tool features from claim 15. Claims 20 – 22 recite the features in claims 2 – 4 and 7, but depend from claim 19. No new matter is presented.

In paragraphs 4 and 5 of the office action, claims 10, 13 and 15 – 17 were indicated as allowed and claims 4 and 9 allowable but objected to as depending on a rejected base claim. Claims 1-3 and 5-7 stand rejected as anticipated by Taylor US2001-0020189, which is now issued as US 6544291. The rejection is, respectfully, traversed.

The office action cites Figs. 5 and 7 of Taylor, which show an anti-reflux valve prosthesis that is anchored in the esophagus at the gastroesophageal junction to treat gastroesophageal reflux disease (GERD), especially where a patient may experience difficulty swallowing due to the presence of a tumor in the esophagus. See paragraph [0009]. The embodiments cited in the office action employ a one-way valve 21 that “permits the easy passage of ingested material through the bore of the housing 83 in one direction, while impeding the reflux of stomach content through the bore of the cylindrical housing 83 in the other direction.” Paragraph [0029]. The valve 21 shown in Fig. 5 is a mitral or bicuspid valve, but could also be another type of one-way or check valve such as a sleeve valve, monocuspid valve, hinged disk valve, double-hinged valve, etc. Paragraph [0031]. “The implanted prosthesis allows normal swallowing to take place in an orthograde manner while preventing the reflux of gastric contents from the stomach into the esophagus.” Paragraph [0005].

In Fig. 5, the tissue anchor array 19 is comprised of straight spikes 27 that are illustrated as extending orthogonally from the mounting ring 13. Paragraph [0035]. In Fig. 7, the tissue anchor array 30 extends radially outwardly from a lower end 83b of the cylindrical housing 83. Paragraph

[0038]. The spikes are compressed as into an overtube during peroral insertion and expanded during implantation to secure the spikes 27 into the esophageal lumen. See paragraphs [0013], [0014] and [0041].

Respectfully, Taylor is directed to an entirely different non-analogous device and is not at all relevant to the present invention. Taylor discloses an anti-reflux valve that facilitates normal efflux for food intake and prevents reflux of gastric fluids into the esophagus to treat GERD, whereas the invention of claims 1-3 and 5-7 is directed to a food intake-limiting device that is used below the gastroesophageal junction in fluid communication with the gastric fluids. Thus the Taylor valve prosthesis comprises a stent having a generally cylindrical housing 83 with bell-shaped ends 83a,83b and a central bore 83c with an inner diameter compatible with orthograde passage of ingested or swallowed food through the lumen of the esophagus. Paragraph [0027]. The bell-shaped ends help secure the prosthesis in location in the esophagus. Paragraph [0032]. Esophageal stents are known to promote more normal swallowing in patients with invasive esophageal tumors. See Dua, Kulwinder and Nunes submitted in an IDS concurrently herewith. Esophageal stents contrast starkly with the present food intake-limiting device of claim 1 wherein both of the inner and outer elements taper

frustoconically from a large radius proximal end to a small radius distal end to define an ingestion chamber to limit a rate of efflux.

The spikes in Taylor protrude outwardly from the housing 83 and push into the esophageal lumen outside the housing, whereas the claim 1 apparatus herein is secured to stomach lining below the esophageal junction. In Taylor, retention of the esophageal lumen thus occurs outside the housing. In the claim 1 apparatus, the stomach lining protrudes through a plurality of openings in the outer element to the inner element wherein retention members hold the protruding stomach lining.

Accordingly, the office action overlooks that Taylor teaches / suggests neither an efflux-limiting ingestion chamber defined by inner and outer elements, nor retention members to hold stomach lining protruding inwardly from the outer element to the inner element. It is respectfully submitted that the present invention as defined in the claims is allowable over Taylor, and the rejection can be withdrawn.

Further examination of the application, as amended, and reconsideration of the rejections and objections are respectfully requested. In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. If any issues remain that are appropriate for resolution, please contact undersigned counsel.

Respectfully submitted,

/Daniel N. Lundeen /  
Daniel N. Lundeen  
Reg. No. 31,177  
Lundeen & Lundeen, PLLC  
PO Box 131144  
Houston, Texas 77219-1144  
(713) 652-2555  
(713) 652-2556 Fax  
ATTORNEY FOR APPLICANT

DNL/ml